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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,481	01/20/2004	Nozer M. Mehta	P/546-280	2921

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EXAMINER	
RUSSEL, JEFFREY E	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 04/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/761,481	MEHTA ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7 sheets*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. The Sequence Listing filed October 20, 2005 is approved.

2. Claims 48, 49, and 51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. There is no antecedent basis in the claims for the phrase "said glycine" at claim 48, line 1. The claims upon which claim 48 depends do not mention glycine. Claim 49 refers to "The pharmaceutical composition of claim 45"; however, claim 45 is drawn to a method, not a pharmaceutical composition. There is no antecedent basis in the claims for the phrase "said pH-lowering compound" at claim 51, lines 1-2. The previous claims use the terminology "pH-lowering agent".

3. Claim 47 is objected to because of the following informalities: At claim 47, line 2, "has" should be deleted. Appropriate correction is required.

4. The effective filing date of instant claims 1-63 is January 21, 2003, the filing date of provisional application 60/441,856. Instant claims 1-63 are deemed to be entitled under 35 U.S.C. 119(e) to the benefit of the filing date of the provisional application because the provisional application, under the test of 35 U.S.C. 112, first paragraph, discloses the claimed subject matter.

The effective filing date of instant claims 64 and 65 is January 20, 2004, the filing date of the instant application. Instant claims 64 and 65 are not deemed to be entitled under 35 U.S.C. 119(e) to the benefit of the filing date of provisional application 60/441,856 because the provisional application, under the test of 35 U.S.C. 112, first paragraph, does not disclose general pharmaceutical compositions for oral delivery in which the lh-rh or PTH 1-34-OH are not amidated.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

For the purposes of this invention, the level of ordinary skill in the art is deemed to be at least that level of skill demonstrated by the patents in the relevant art. Joy Technologies Inc. v. Quigg, 14 USPQ2d 1432 (DC DC 1990). One of ordinary skill in the art is held accountable not only for specific teachings of references, but also for inferences which those skilled in the art may reasonably be expected to draw. In re Hoeschele, 160 USPQ 809, 811 (CCPA 1969). In addition, one of ordinary skill in the art is motivated by economics to depart from the prior art to

reduce costs consistent with desired product properties. In re Clinton, 188 USPQ 365, 367 (CCPA 1976); In re Thompson, 192 USPQ 275, 277 (CCPA 1976).

6. Claims 45-48, 50, 51, 54, 56, and 63 are rejected under 35 U.S.C. 102(b) as being anticipated by Stern et al (U.S. Patent No. 5,912,014). Stern et al teach oral administration of salmon calcitonin using a carrier comprising a pH-lowering agent, an absorption enhancer, a non-physiologically active protein, a gelatin capsule, and an enteric coating. The salmon calcitonin is made with a C-terminal glycine extension which is enzymatically converted to an amide group. See, e.g., column 4, line 63 - column 9, line 10, and claims 1-32. Note that the instant method claims, in contrast to the instant composition claims, do not require the peptide agent to be amidated at a site that is not naturally amidated.

7. Claims 45-47, 50, 51, 54, 56, 61, 63, and 64 are rejected under 35 U.S.C. 102(b) as being anticipated by Stern et al (U.S. Patent No. 6,086,918). Stern et al teach oral administration of peptides such as insulin, salmon calcitonin, parathyroid hormone, and lhrf using a carrier comprising a pH-lowering agent, an absorption enhancer, a non-physiologically active protein, a gelatin capsule, and an enteric coating. See, e.g., column 6, line 1 - column 12, line 10, and claims 1-55. Salmon calcitonin and lhrf (which is the same as LHRH) are amidated at their C-termini in their naturally-occurring forms. Note that the instant method claims, in contrast to the instant composition claims, do not require the peptide agent to be amidated at a site that is not naturally amidated.

8. Claims 1-8, 12-47, 49-51, 54-60, 62, 63, and 65 are rejected under 35 U.S.C. 103(a) as being obvious over Stern et al (U.S. Patent No. 6,086,918) as applied against claims 45-47, 50, 51, 54, 56, 61, 63, and 64 above, and further in view of Habener (U.S. Patent No. 5,120,712), Balschmidt et al (U.S. Patent No. 5,157,021), Barbier et al (U.S. Patent No. 6,110,892), the

European Patent Application 878,201, or Neiss et al (U.S. Patent No. 4,804,742). Stern et al do not teach peptides which are amidated GLP-1 analogs, amidated insulin analogs, or amidated PTH analogs. Habener teaches GLP-1 analogs which are amidated. See, e.g., claims 1 and 4. Balschmidt et al teach insulin in which the carboxylic acid groups present in the sidechains at residues A4, A17, B13, and B21 are amidated in order to achieve a long-lasting protracted acting insulin analog. See, e.g., column 2, lines 5-8 and 49-53. Barbier et al teach the human parathyroid hormone derivatives hPTH(1-34)-OH and hPTH(1-31)NH_2. See, e.g., column 2, lines 26-44. The European Patent Application '201 teaches the human parathyroid hormone derivative hPTH(1-34)NH_2. See, e.g., column 3, lines 31-36. Neiss et al teach salmon calcitonin amidated at locations which are not naturally amidated and which have extended duration of activity. See, e.g., column 1, lines 42-44, and claims 1 and 2. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to use the specific peptides of Habener, Balschmidt et al, Barbier et al, the European Patent Application '201, or Neiss et al in the oral administration compositions of Stern et al because the oral administration compositions of Stern et al have general applicability to any peptide and because it would be desirable to be able to administer orally the peptides of Habener, Balschmidt et al, Barbier, the European Patent Application '201, and Neiss et al because oral administration is easier for the patient. With respect to instant claim 5, process limitations do not impart novelty and unobviousness to product-by-process claims where the product is otherwise anticipated by or obvious over the prior art.

9. Claims 45-48, 50-54, 56, 61, and 63 are rejected under 35 U.S.C. 102(a), and claim 64 is rejected under 35 U.S.C. 102(b), as being anticipated by the WO Patent Application 02/043767.

The WO Patent Application '767 teaches oral administration of peptides such as insulin, salmon calcitonin, parathyroid hormone, lhrf, and GLP-1 linked to a membrane translocator using a carrier comprising a pH-lowering agent, a protease inhibitor, an absorption enhancer, a non-physiologically active peptide, a gelatin capsule, and an enteric coating. See, e.g., page 17, lines 13-22, page 18, lines 10-27, page 20, lines 11-29, and claims 1-57. Salmon calcitonin and lhrf (which is the same as LHRH) are amidated at their C-termini in their naturally-occurring forms. Note that the instant method claims, in contrast to the instant composition claims, do not require the peptide agent to be amidated at a site that is not naturally amidated. [Note that the WO Patent Application '767 does not designate the US, and therefore is not available as prior art under 35 U.S.C. 102(e).]

10. Claims 1-47, 49-60, 62, 63, and 65 are rejected under 35 U.S.C. 103(a) as being obvious over the WO Patent Application 02/043767 as applied in the above rejection of claims 45-48, 50-54, 56, 61, and 63, and further in view of Habener (U.S. Patent No. 5,120,712), Balschmidt et al (U.S. Patent No. 5,157,021), Barbier et al (U.S. Patent No. 6,110,892), the European Patent Application 878,201, or Neiss et al (U.S. Patent No. 4,804,742). The WO Patent Application '767 does not teach peptides which are amidated GLP-1 analogs, amidated insulin analogs, or amidated PTH analogs. Habener teaches GLP-1 analogs which are amidated. See, e.g., claims 1 and 4. Balschmidt et al teach insulin in which the carboxylic acid groups present in the sidechains at residues A4, A17, B13, and B21 are amidated in order to achieve a long-lasting protracted acting insulin analog. See, e.g., column 2, lines 5-8 and 49-53. Barbier et al teach the human parathyroid hormone derivatives hPTH(1-34)-OH and hPTH(1-31)NH_2. See, e.g., column 2, lines 26-44. The European Patent Application '201 teaches the human parathyroid

hormone derivative hPTH(1-34)NH_2. See, e.g., column 3, lines 31-36. Neiss et al teach salmon calcitonin amidated at locations which are not naturally amidated and which have extended duration of activity. See, e.g., column 1, lines 42-44, and claims 1 and 2. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to use the specific peptides of Habener, Balschmidt et al, Barbier et al, the European Patent Application '201, or Neiss et al in the oral administration compositions of the WO Patent Application '767 because the oral administration compositions have general applicability to any peptide and because it would be desirable to be able to administer orally the peptides of Habener, Balschmidt et al, Barbier et al, the European Patent Application '201, and Neiss et al because oral administration is easier for the patient. With respect to instant claim 5, process limitations do not impart novelty and unobviousness to product-by-process claims where the product is otherwise anticipated by or obvious over the prior art.

11. Claims 1, 6, and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Balschmidt et al (U.S. Patent No. 5,157,021). Balschmidt et al teach pharmaceutical compositions comprising insulin in which the carboxylic acid groups present in the sidechains at residues A4, A17, B13, and B21 are amidated in order to achieve a long-lasting protracted acting insulin analog. See, e.g., column 2, lines 5-8 and 49-53; column 3, line 64 - column 4, line 3; and claims 1-16. Note that an intended use limitation, e.g., "for oral delivery", does not impart patentability to product claims where the product is otherwise anticipated by the prior art.

12. Claims 1, 4, 5, and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Habener (U.S. Patent No. 5,120,712). Habener teaches pharmaceutical compositions comprising GLP-1 analogs which are amidated at the C-terminus. See, e.g., column 4, lines 14-29, and

claims 1, 4, 5, and 7. Note that an intended use limitation, e.g., "for oral delivery", does not impart patentability to product claims where the product is otherwise anticipated by the prior art. With respect to instant claim 5, process limitations do not impart novelty and unobviousness to product-by-process claims where the product is otherwise anticipated by or obvious over the prior art.

13. Claims 1, 4, 5, 40, and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Barbier et al (U.S. Patent No. 6,110,892). Barbier et al teach pharmaceutical compositions comprising hPTH(1-31)NH_2. See, e.g., column 9, lines 25-46. Note that an intended use limitation, e.g., "for oral delivery", does not impart patentability to product claims where the product is otherwise anticipated by the prior art. With respect to instant claim 5, process limitations do not impart novelty and unobviousness to product-by-process claims where the product is otherwise anticipated by or obvious over the prior art.

14. Claims 1, 4, 5, 40, 42, 45, 47, 58, and 60 are rejected under 35 U.S.C. 102(e) as being anticipated by Peri et al (U.S. Patent Application Publication 2004/0023882). Peri et al teach pharmaceutical compositions comprising hPTH(1-34) amidated at its C-terminus, including hPTH(1-34)NH_2. The compositions can be administered orally. See, e.g., paragraph [0064] and claims 1-2. With respect to instant claim 5, process limitations do not impart novelty and unobviousness to product-by-process claims where the product is otherwise anticipated by or obvious over the prior art.

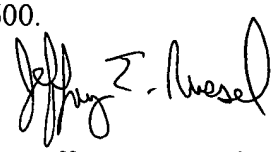
The subject matter disclosed by Peri et al and relied upon in the rejection is also disclosed in the provisional application, 60/378,082, upon which Peri et al claim priority under 35 U.S.C. 119(e). See, e.g., page 10, line 22, and claims 1 and 2 of the provisional application.

Accordingly, Peri et al is available as prior art against the instant claims under 35 U.S.C. 102(e).

15. The references crossed off the Information Disclosure Statement filed September 7, 2004 are duplicate citations.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

April 4, 2006